K131750

MAR - 6 2014

510(k) Summary

Submitter:	Apex Biotechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN)
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Date Prepared:	February 17, 2014
Trade Names:	AutoSure HT Blood Glucose Monitoring System AutoSure HT Blood Glucose Test Strips Contrex Plus 4 Glucose Control Solutions
Classification:	Glucose test system, 21 CFR 862.1345, Class II Single (specified) analyte controls (assayed and unassayed), Class I, 21 CFR 862.1660
Product Codes:	CGA, NBW; JJX
Predicate Devices:	GAL-1A Blood Glucose Monitoring System (k113208) Contrex Plus III Glucose Control Solutions (k113098)
Device Description:	The AutoSure HT blood glucose meter and AutoSure HT test strips are used for testing of blood glucose. Contrex Plus 4 Glucose Control Solutions are used for quality control testing of the systems.

510(k) Summary (Continued)

Intended Use:	AutoSure HT Blood Glucose Monitoring System The AutoSure HT Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use). It is indicated for lay use by people with diabetes, as an aid to monitoring levels in Diabetes Mellitus and should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use. AutoSure HT Blood Glucose Test Strips The AutoSure HT Blood Glucose Test Strips are to be used with the AutoSure HT Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. Contrex Plus 4 Glucose Control Solutions The Contrex Plus 4 glucose control solution is used with the AutoSure HT meter and AutoSure HT test strips to verify that the meter and test strips are working together properly and that the test is performing correctly.
Comparison of Technological Characteristics:	The AutoSure HT meter has been modified relative to the predicate by minor changes in external design and modifications of the test strip holder to support the hematocrit compensation feature. Meter software has been augmented to support the hematocrit compensation feature. The AutoSure HT test strip has been modified relative to the predicate by minor changes in chemistry [17% increase in glucose oxidase, 6% increase in electron shuttle], alteration of electrode tracks to support 8 calibration codes, and addition of a second blood channel to support the hematocrit compensation feature. The chemistry of the Contrex Plus 4 control solutions has been modified slightly to increase viscosity.

510(k) Summary (Continued)

Non-Clinical Testing:	Testing was conducted as follows: EMC and Electrical Safety, test strip holder reliability testing, battery life verification, drop testing, disinfection performance (robustness of meter to multiple cleanings and disinfections), software verification and validation, and linearity testing with validation of Lo/Hi detection, temperature and humidity testing, sample volume verification, precision testing, interferences testing, altitude testing, qualification of control solutions, hematocrit performance testing, Disinfection testing with recommended disinfectant wipes was done using an animal virus test model. Results demonstrate substantial equivalence to the predicate system.
Clinical Testing	An accuracy study was conducted with blood testing at finger, palm, and forearm sites by healthcare professionals. A User Performance study was conducted with self-testing at finger, palm, and forearm sites by home users, including evaluation of ease of use and ease of understanding of the user manual. Results demonstrate substantial equivalence to the predicate system.
Conclusion:	Clinical and non-clinical testing demonstrated that the AutoSure HT system performs in a substantially equivalent manner to that of the predicate. We conclude that the AutoSure HT system is substantially equivalent to the predicate system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 6, 2014

APEX BIOTECHNOLOGY CORP.
HSUE-MEI LEE,MANAGER, QA
NO. 7, LI-HSIN ROAD V,
HSINCHU SCIENCE PARK
HSINCHU 30078, CHINA (TAIWAN)

Re: K131750
Trade/Device Name: AutoSure HT Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CGA, NBW, JJX
Dated: January 24, 2014
Received: January 28, 2014

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
k131750

Device Name
AutoSure HT Blood Glucose Monitoring System

Indications for Use *(Describe)*

The AutoSure HT Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use). It is indicated for lay use by people with diabetes, as an aid to monitoring levels in Diabetes Mellitus and should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

The AutoSure HT Blood Glucose Test Strips are to be used with the AutoSure HT Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm.

The Contrex Plus 4 glucose control solution is used with the AutoSure HT meter and AutoSure HT test strips to verify that the meter and test strips are working together properly and that the test is performing correctly.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Katherine Serrano -S